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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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09/856,927

09/19/2001

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015280-382100US

6490

7590

03/17/2004

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/856,927 | DEAN ET AL. | |
| | Examiner | Art Unit | |
| | Sheela J Huff | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on 2/23/04 has been considered.

Claims 1-2 and 21 are pending.

Response to Arguments

Claim Rejections - 35 USC § 112

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection are of record in the paper mailed 8/21/03.

Applicant argues the claim 1 sets forth both structural and functional features as require by case law. With respect to structural features applicant argues that specific binding between an antibody and the requires a specific epitope (ie structural feature). While this is true in general, in the instant application applicant has not defined the epitope that the antibodies bind to. In fact, the claim does not even limit the claimed protein as containing the epitope that the antibodies bind to. The claim reads on any protein that contains the epitope. Thus, applicant has not provided sufficient structural information.

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With respect to functional features, applicant argues that the claim also defines the functional feature. Applicant has not described what portions of the protein are required for the function, what kinds of modifications can be tolerated by the protein to retain function.

Thus, in view of the above, applicant was not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 remains rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98) (reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03). The reasons for this rejection are of record in the paper mailed 8/21/03.

Applicant argues that the declaration shows that applicant had possession of Seq ID No. 1 and 2 prior to 2/5/98. The declaration does show this. However, the reference protein is 99.8% identical to SEQ ID NO. 2 and applicant has not that they have

possession of such a protein prior to 2/5/98. In order for the 131 declaration to be effective, it must show that applicant had reduced to practice what is shown by the reference.

Claims 1 and 2 remain rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98) (reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03). The reasons for this rejection are of record in the paper mailed 8/21/03.

Applicant's arguments have been addressed above.

Claim 1 remains rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98). The reasons for this rejection are of record in the paper mailed 8/21/03.

Applicant's arguments have been addressed above.

Claims 1 and 2 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98). The reasons for this rejection are of record in the paper mailed 8/21/03.

Applicant's arguments have been addressed above.

Allowable Subject Matter

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sheela J Huff
Primary Examiner
Art Unit 1642

sjh